

We claim:

1. A method of manufacturing a shaped bone graft substitute comprising the step of:  
  
compressing a granulated bone material into said shape.
2. The method of claim 1, wherein said bone material is an allograft material, a ceramic material, a polymer or combinations thereof.
3. The method of claim 1, wherein said material further comprises a processing aid composition.
4. The method of claim 3, wherein said processing aid composition is selected from the group consisting of stearic acid, calcium stearate, magnesium stearate, natural polymer, synthetic polymer, sugar and combinations thereof.
5. The method of claim 4, wherein said natural polymer is starch, gelatin, or combinations thereof.
6. The method of claim 4, wherein said synthetic polymer is methylcellulose, sodium carboxymethylcellulose, or hydropropylmethylcellulose.
7. The method of claim 4, wherein said sugar is glucose or glycerol.
8. The method of claim 2, wherein said allograft bone material is cortical-cancellous bone.
9. The method of claim 2, wherein said allograft bone material is demineralized bone matrix.
10. The method of claim 1, wherein said shape is a three-dimensional intricate shape.
11. The method of claim 1, wherein said shape is selected from the group consisting of a jack, a tablet, a strip, a block, a cube, a chip, a pellet, a pill, a lozenge, a sphere, a ring, and combinations thereof.
12. The method of claim 10, wherein said shape is a JAX<sup>TM</sup> particle.
13. The method of claim 10, wherein said shape is a jack, a JAX<sup>TM</sup>, or a ring.

14. The method of claim 2, wherein said ceramic material is selected from the group consisting of hydroxylapatite, calcium sulphate, alumina, silica, calcium carbonate, calcium phosphate, calcium tartarate, bioactive glass, and combinations thereof.
15. The method of claim 1, wherein said substitute further comprises a biological agent.
16. The method of claim 15, wherein said biological agent is added to said material prior to said compaction step.
17. The method of claim 15, wherein said biological agent is added to said bone graft substitute subsequent to said compaction step.
18. The biological agent of Claim 15, wherein said agent is selected from the group consisting of a growth factor, an antibiotic, a strontium salt, a fluoride salt, a magnesium salt, a sodium salt, a bone morphogenetic factor, a chemotherapeutic agent, a pain killer, a bisphosphonate, a bone growth agent, an angiogenic factor, and combinations thereof.
19. The growth factor of Claim 18 wherein said growth factor is selected from the group consisting of platelet derived growth factor (PDGF), transforming growth factor b (TGF-b), insulin-related growth factor-I (IGF-I), insulin-related growth factor-II (IGF-II), fibroblast growth factor (FGF), beta-2- microglobulin (BDGF II), bone morphogenetic protein (BMP), and combinations thereof.
20. The antibiotic of Claim 18, wherein said antibiotic is selected from the group consisting of tetracycline hydrochloride, vancomycin, cephalosporins, and aminoglycosides such as tobramycin, gentamicin, and combinations thereof.
21. The bone morphogenetic factor of Claim 18, wherein said factor is selected from the group consisting of proteins of demineralized bone, demineralized bone matrix (DBM), bone protein (BP), bone morphogenetic protein (BMP), osteonectin, osteocalcin, osteogenin, and combinations thereof.
22. The chemotherapeutic agent of Claim 18, wherein said agent is selected from the group consisting of cis-platinum, ifosfamide, methotrexate, doxorubicin hydrochloride, and combinations thereof.

23. The pain killer of Claim 18, wherein said pain killer is selected from the group consisting of lidocaine hydrochloride, bipivacaine hydrochloride, non-steroidal anti-inflammatory drugs such as ketorolac tromethamine, and combinations thereof.
24. The method of claim 1, wherein particles of said material are less than about 10 millimeters in diameter.
25. The method of claim 1, wherein particles of said material are less than about 250 $\mu$ m in diameter.
26. The method of claim 1, wherein particles of said material are in a range of about 50 to 180 microns.
27. A method of manufacturing a bone graft substitute comprising the steps of:
- obtaining a bone material;
  - pulverizing said material to produce a granulated bone material; and
  - subjecting said granulated bone material to a powder compaction process.
28. The method of claim 27, wherein said powder compaction process utilizes a withdrawal press, wherein said press comprises:
- a stationary lower punch;
  - a moveable die;
  - a moveable upper punch; and
  - a moveable lower punch, wherein said stationary lower punch is contained within said moveable lower punch.
29. The method of claim 27, wherein said powder compaction process utilizes a withdrawal press, wherein said press comprises:
- a stationary lower punch;

a moveable lower punch, wherein said stationary lower punch is contained within said moveable lower punch;

a stationary upper punch;

a moveable upper punch, wherein said stationary upper punch is contained within said moveable lower punch; and

a moveable die.

30. A method of manufacturing a shaped bone graft substitute from granulated bone material, said method comprising the steps of:

providing a stationary lower punch and a moveable lower punch which is vertically moveable about the stationary lower punch, a moveable die having at least one cavity and positionable generally above the stationary lower punch, and a moveable upper punch;

introducing the granulated bone material into the cavity;

positioning the moveable die generally above the stationary lower punch;

moving the moveable upper punch to pressably contact the material in opposition to the moveable lower punch and stationary lower punch; and

moving the moveable lower punch to pressably contact the material in opposition to the moveable upper punch,

whereby said moving steps form the material into the shaped bone graft substitute.

31. The method of claim 30, wherein the steps of moving the upper and lower punches effect a substantially uniform distribution of pressure within said material.

32. The method of claim 30, wherein the punches are configured such that the shape of the bone graft substitute resulting from the moving steps is a shape selected from the group consisting of a JAX<sup>TM</sup> particle, a jack, a tablet, a strip, a block, a cube, a pellet, a pill, a lozenge, a sphere, and a ring.

33. The method of claim 30, wherein at least one of the moving steps applies a force to the material in a range of about 0.2 to about 5 tons.

34. The method of claim 30, wherein at least one of the moving steps applies a force to the material in a range of about 0.2 to about 2 tons.

35. The method of claim 30, wherein at least one of the moving steps applies a force to the material in a range of about 0.5 to about 1 ton.

36. The method of claim 30, wherein said moving step of the moveable lower punch to the material is subsequent to the moving step of the moveable upper punch to the material.

37. A method of manufacturing a shaped bone graft substitute from granulated bone material, said method comprising the steps of:

introducing an amount of the granulated bone material into the cavity;

providing a lower punch assembly, an upper punch assembly, and a moveable die positionable generally above the lower punch assembly;

positioning the moveable die generally above the lower punch assembly;

moving the lower punch assembly in opposition to the moveable upper punch to pressably contact the material;

moving the upper punch assembly in opposition to the moveable lower punch to pressably contact the material,

whereby said moving steps form the material into the shaped bone graft substitute.

38. The method of claim 37, wherein the lower punch assembly is comprised of at least one of a stationary lower punch and a moveable lower punch vertically moveable about the stationary lower punch.

39. The method of claim 37, wherein the upper punch assembly is comprised of at least one of a stationary upper punch and a moveable upper punch vertically moveable about the stationary upper punch.

40. An apparatus for shaping a bone graft substitute from granulated bone material, said apparatus comprising:

a stationary lower punch having a top surface;

a moveable lower punch vertically moveable about the stationary lower punch and having a top surface;

a moveable die having at least one cavity and positionable generally above the stationary lower punch; and

a moveable upper punch,

such that said moveable upper punch moves in opposition to said moveable lower punch to pressably contact the material contained within the cavity, whereupon following pressably contacting the material by the moveable lower punch the top surface height of the lower moveable punch is above the top surface height of the stationary lower punch.

41. A method for manufacturing a bone graft substitute from granulated bone material, said method comprising the steps of:

providing:

a first punch assembly having a first contact surface configured to effect a relief profile onto a first surface of the granulated bone material;

a second punch assembly having a second contact surface; and

a moveable die having at least one cavity;

introducing the bone material into the cavity;

positioning the moveable die generally in alignment with the first punch assembly;

moving at least a portion of the first punch assembly to pressably contact the material in opposition to the second punch assembly to effect the desired relief profile on the first surface thereof; and

moving at least a portion of the second punch assembly to pressably contact the material in opposition to the first punch assembly,

whereby said moving steps form the material into the shaped bone graft substitute.

42. A method for manufacturing a bone graft substitute from demineralized bone matrix material, said method comprising the steps of:

providing:

a first punch assembly having a first contact surface configured to effect a relief profile onto a first surface of the demineralized bone matrix material;

a second punch assembly having a second contact surface; and

a moveable die having at least one cavity;

introducing the demineralized bone matrix material into the cavity;

positioning the moveable die generally in alignment with the first punch assembly;

moving at least a portion of the first punch assembly to pressably contact the material in opposition to the second punch assembly to effect the desired relief profile on the first surface thereof; and

moving at least a portion of the second punch assembly to pressably contact the material in opposition to the first punch assembly,

whereby said moving steps form the material into the shaped bone graft substitute.

43. The method of claim 41, wherein the contact surface area of the first punch assembly is generally equivalent to a contact surface area of the second punch assembly such that the moving steps apply a substantially uniform pressure distribution to the material.

44. The method of claim 41, wherein the first punch assembly includes a stationary punch and a moveable punch, such that the steps of moving the first punch assembly includes moving the moveable punch to pressably contact the material.

45. The method of claim 41, wherein the second punch assembly includes a stationary punch and a moveable punch, such that the steps of moving the first punch assembly includes moving the moveable punch to pressably contact the material.

46. An apparatus for manufacturing a bone graft substitute from a granulated bone material, said apparatus comprising:

a first punch assembly having a first contact surface having a profile configured to effect a relief profile onto a surface of the bone material;

a second punch assembly having a second contact surface, the second contact surface positioned in general alignment with the first contact surface; and

a moveable die having at least one cavity, the moveable die being positionable generally in between the first and second punch assemblies.

47. As a composition of matter, a bone graft substitute manufactured by the method of claim 1.

48. As a composition of matter, a bone graft substitute manufactured by the method of claim 2.

49. As a composition of matter, a bone graft substitute manufactured by the method of claim 9.

50. As a composition of matter, a bone graft substitute manufactured by the method of claim 12.

51. As a composition of matter, a bone graft substitute manufactured by the method of claim 27.

52. As a composition of matter, a bone graft substitute manufactured by the method of claim 30.

53. As a composition of matter, a bone graft substitute manufactured by the method of claim 37.

54. As a composition of matter, a bone graft substitute manufactured by the method of claim 41.

55. As a composition of matter, a bone graft substitute manufactured by the method of claim 42.



56. As a composition of matter, a bone graft substitute manufactured with the apparatus of claim 40.

57. As a composition of matter, a bone graft substitute manufactured with the apparatus of claim 46.